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National
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Program

Quality System Manual

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NVLAP®

National Voluntary Laboratory Accreditation Program

Quality System Manual

- Revised October 1997

NISTIR 5589

U.S. Department of Commerce
- William M. Daley, Secretary

Technology Administration
- Gary R. Bachula, Acting Under Secretary for Technology

National Institute of Standards and Technology
- Robert E. Hebner, Acting Director

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QUALITY SYSTEM MANUAL

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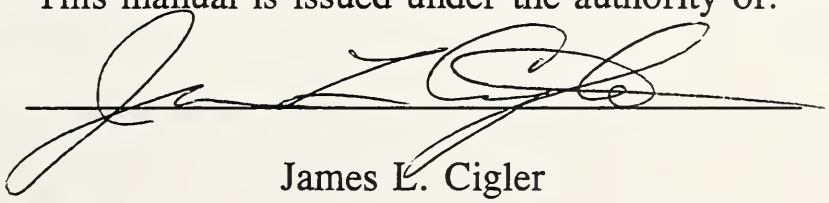

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PURPOSE OF THIS MANUAL

The purpose of this manual is to describe the policies and control structure of the quality management system used to achieve the mission of the National Voluntary Laboratory Accreditation Program (NVLAP).

MISSION STATEMENT

The mission of the National Voluntary Laboratory Accreditation Program (NVLAP) is to provide the highest quality accreditation services to its customers and to be recognized nationally and internationally as a "world class" laboratory accreditation organization.

The success of the NVLAP quality management system is first and foremost dependent on a trained and motivated staff committed to quality and productivity. The quality management system is designed to provide to the staff the policy, procedures, and guidance necessary to achieve the Mission Statement and Objectives (Sec. 1.1.1). Because the quality of NVLAP's services is and will continue to be the key to its value and effectiveness in the 1990s and beyond, it is increasingly vital for all NVLAP employees to understand and use the quality management system to do a good job—the first time and every time.

The quality management system operated by NVLAP is based on established principles of formalized modern quality assurance. These principles are documented in a number of national and international standards and guides for quality systems as applied to a wide range of industries. In particular, the quality management system described in this manual addresses:

- the requirements of the ISO (International Organization for Standardization) Quality Standards as defined in ISO 9001:1994 and ANSI (American National Standards Institute)/ASQC (American Society for Quality Control) Q9001-1994;

- the requirements for accreditation bodies contained in ISO/IEC Guide 58: 1993, *Calibration and Testing Laboratory Accreditation Systems—General Requirements for Operation and Recognition*; and

- the requirements under which NVLAP operates as set forth in the U.S. Code of Federal Regulations (CFR), Title 15, Part 285, and augmented by NIST Handbook 150, *NVLAP Procedures and General Requirements*.

ORGANIZATION OF THIS MANUAL

The NVLAP Quality System Manual (hereinafter referred to as the QSM) is formatted into sections which parallel the clauses contained in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994. The QSM contains nine appendices which contain supportive information essential to an understanding of the system:

- Appendix A is a list of acronyms used in the QSM;
- Appendix B is a list of references used in developing NVLAP's quality system documentation, and with which the system is compatible;
- Appendix C illustrates the organization of NVLAP's internal committees;
- Appendix D presents the table of contents of NIST Handbook 150, *NVLAP Procedures and General Requirements*;
- Appendix E presents the table of contents of the *NVLAP Administrative Procedures Manual*;
- Appendix F presents the table of contents of the *NIST Administrative Manual*;
- Appendix G presents the list of holders of controlled copies of the QSM;
- Appendix H is an example of the confirmation slip for change control of the QSM; and
- Appendix I is a copy of the memorandum from the Director of NIST confirming the delegation of certain designated authority to the NVLAP Chief.

1.0 MANAGEMENT RESPONSIBILITY

Section 1 of the QSM addresses the requirements of clauses 4.1.1 (Quality Policy), 4.1.2 (Organization), and 4.1.3 (Management Review) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

1.1 QUALITY POLICY

1.1.1 The policy for and commitment to quality by NVLAP's management and staff are reflected in its Mission Statement and in the Objectives for Quality listed below:

1.1.1.1 Establish and maintain international recognition through compatibility with the requirements of ISO quality standards as defined in ISO/IEC Guides 58 and 25, ISO 9000 Standard Series, and associated guides and standards.

1.1.1.2 Maintain NVLAP's reputation for quality throughout the 1990's and beyond by:

- fostering continuous process improvement and problem prevention;
- understanding and using the quality system to do a good job—the first time and every time;
- providing quality services by striving to fulfill and exceed the needs and expectations of NVLAP-accredited laboratories;
- forming relationships with both laboratories and contractors that will improve quality in all aspects of services; and
- maintaining close association with comparable national and international accreditation and standards development organizations.

1.1.1.3 Fully involve the NVLAP staff, assessors, consultants, and contractors in the quality system through:

- the commitment of each person to excellence;
- quality awareness training, continuously reinforced by management to ensure understanding and commitment;
- training and support of all employees needed to provide quality services to all laboratories;
- assigning individual responsibilities, authority, and accountability;

- establishing and maintaining a working environment that supports the development of high-quality laboratory accreditation programs;
- recognizing both individual and group quality improvement achievements;
- developing and maintaining a team approach that emphasizes enhancing the effectiveness of NVLAP through increased quality and productivity;
- providing an atmosphere that encourages every NVLAP employee to achieve his or her full potential and pride in workmanship; and
- communicating with NVLAP's customers to determine their needs and requirements to continuously raise quality levels.

1.1.2 NVLAP's quality policy (as embodied in its Mission Statement and Objectives for Quality) is displayed openly as a sign of its pride and commitment, and as a clear reminder of its vision and direction. The policy is presented to all new employees through training, and is continuously reinforced by management to ensure understanding and commitment at all levels of NVLAP.

1.1.3 The procedures under which NVLAP operates, set forth in 15 CFR Part 285 and in NIST Handbook 150, *NVLAP Procedures and General Requirements*, are administered in a nondiscriminatory manner. Access to NVLAP's accreditation system is not conditional upon the size of a laboratory or membership of any association or group.

James L. Cigler, NVLAP Chief — 10/1/97 Date

1.2 ORGANIZATIONAL STRUCTURE AND LINE OF AUTHORITY

1.2.1 NVLAP is a program within the National Institute of Standards and Technology (NIST), an agency of the U.S. Department of Commerce (DOC). NVLAP operates in accordance with Title 15 of the U.S. Code of Federal Regulations (CFR), Part 285 (see fig. 1.1).

1.2.2 DOC Department Organization Order 30-2A, issued October 31, 1995, delegates authority to the Director of NIST to operate NVLAP (as authorized and defined under 15 CFR Part 285).

1.2.3 The Director has redelegated certain designated authority to the Chief of NVLAP, specifically:

- responsibility for all NVLAP accreditation actions, including granting, maintaining, extending, suspending, or withdrawing any NVLAP accreditation, and

- responsibility for the establishment of laboratory accreditation programs (LAPs).

The memorandum confirming this delegation of authority is contained in Appendix I.

1.2.4 NVLAP consists of a headquarters, technical groups, and a business operations group. The organizational structure shown in figure 1.2 illustrates the interrelations and authority of personnel who manage, perform, and verify work affecting the quality of accreditation services provided by NVLAP.

1.2.5 The Management Committee consists of the NVLAP Chief (chair), Deputy Chief, Senior Program Managers, Technical Advisor, and Business Manager. The committee meets regularly to monitor progress and to discuss, plan, and oversee operations development and quality management.

1.2.6 Membership of NVLAP internal committees is shown in Appendix C.

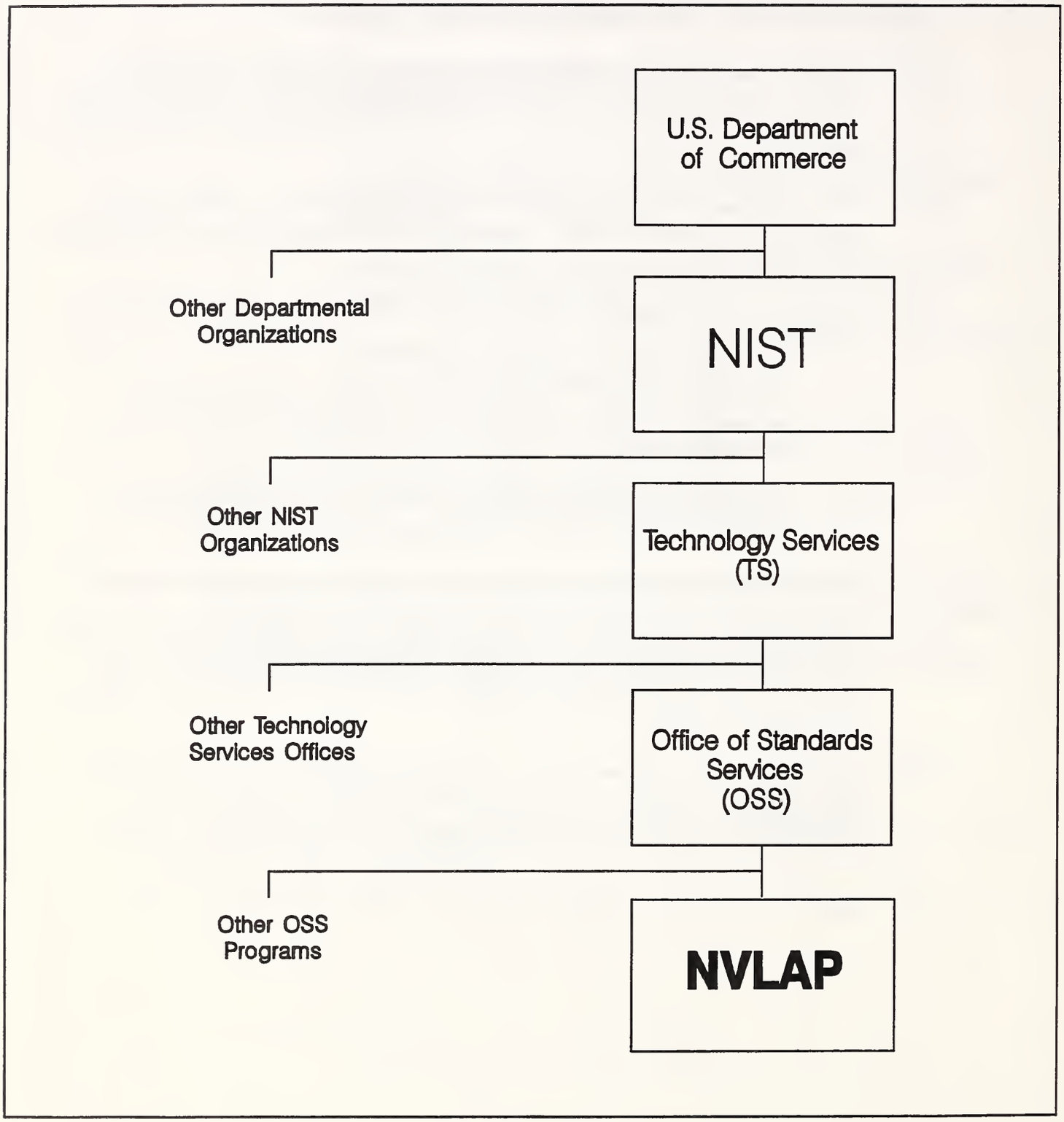

Figure 1.1. NVLAP Within the U.S. Department of Commerce

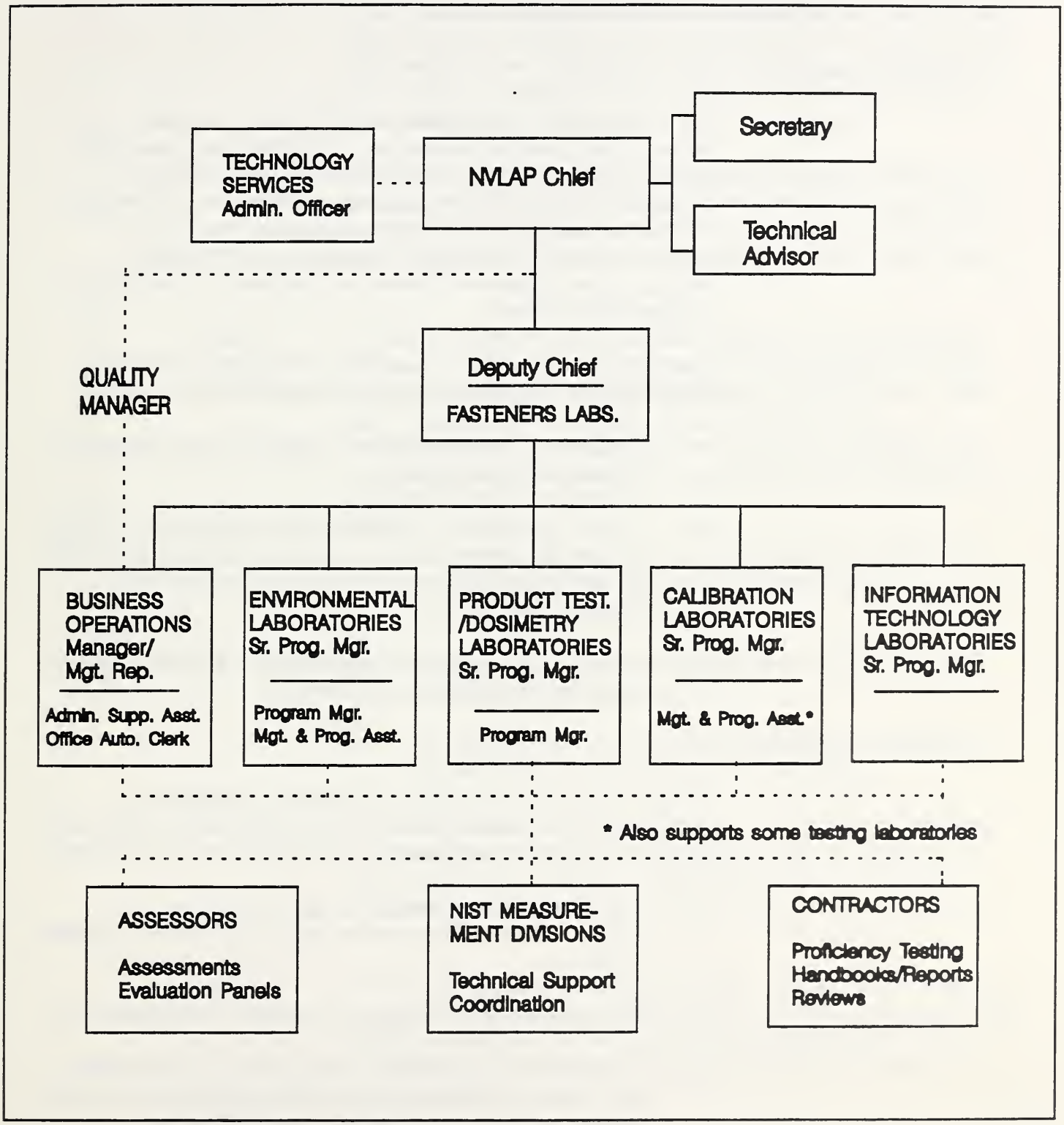

Figure 1.2. NVLAP Organizational Structure

1.3 STAFF FUNCTIONS AND RESPONSIBILITIES

1.3.1 General

1.3.1.1 The authorities and responsibilities of all NVLAP personnel are defined in their position descriptions. A position description is an official, written statement of the major duties, responsibilities, supervisory relationships, and minimum qualifications of a position. Position descriptions and other official personnel records are maintained by the NIST Office of Personnel and Civil Rights. Working copies of personnel records are maintained by the NVLAP Administrative Officer.

1.3.1.2 Quality is the responsibility of each NVLAP employee. NVLAP personnel have sufficient authority and organizational freedom to:

- identify and document problems relating to the accreditation process and quality system;
- initiate, recommend, or provide solutions through the NVLAP Quality Committee (see Sec. 1.3.5) for continuous quality and process improvement, and verify the implementation of solutions; and
- terminate processing upon identification of a nonconformance until corrective actions are implemented.

1.3.2 Staff Positions

1.3.2.1 NVLAP is managed by the Chief of Laboratory Accreditation (NVLAP Chief) who reports to the Director of the Office of Standards Services. In regard to responsibilities for quality, the NVLAP Chief:

- has the overall responsibility for the development, implementation, and continuous nurturing of NVLAP's quality system;
- sets the example in commitment to quality management; and
- ensures that all staff members are qualified to perform their jobs, understand the requirements and operation of the quality system, and have clearly defined responsibilities and authorities needed to fulfill the objectives of the quality system.

1.3.2.2 The Deputy Chief manages the day-to-day operations of the technical groups, serves as Acting Chief in the Chief's absence, ensures that an information system is maintained for the collection and dissemination of laboratory accreditation data, and chairs the information systems committee (Appendix C).

1.3.2.3 Each technical group is managed by a Senior Program Manager who is supported by a Program Manager(s) and Management and Program Assistant(s), as required. [Hereinafter, the term *Program Manager* shall refer to both the Senior Program Manager and Program Manager positions.]

1.3.2.4 NVLAP Program Managers manage all stages of the accreditation process for their assigned laboratory accreditation programs (LAPs) and ensure that NVLAP's quality policies are carried out on a daily basis. Program Managers may delegate the authority for implementation of the quality functions within their assigned LAPs (e.g., data entry), but retain the responsibility for those functions. Program Managers also ensure:

- the participation of those who are technically proficient and otherwise concerned with the establishment and implementation of LAPs;
- the documentation of technical requirements that represent qualified technical opinion; and
- the development and maintenance of definitive checklists for use by NVLAP assessors for on-site assessments.

1.3.2.5 The Business Manager oversees the business operations of NVLAP, including customer service, and participates in the development of information systems. Responsibilities include records and forms management, publications and document control, and supervision of clerical staff.

1.3.2.6 The Administrative Officer is not a member of the NVLAP staff, but is assigned by the Office of Technology Services to provide fiscal and administrative support to NVLAP, including interactions with the NIST budget, accounting, personnel, procurement, and property management departments.

1.3.2.7 The Management and Program Assistants provide support to Program Managers with the management of their assigned LAPs. Responsibilities include maintenance of accreditation data in the

NVLAP Information System (NIS), assistance with accounting, budgetary and financial management functions, processing of laboratory applications and fees, and serving as the primary liaisons between NVLAP and its customer laboratories for nontechnical issues.

1.3.2.8 The NVLAP Secretary provides secretarial support to the NVLAP Chief and Deputy Chief, and performs other administrative duties in support of the office which include timekeeping, travel arrangements, maintaining the administrative files and *NIST Administrative Manual*, and coordinating NVLAP's exhibits at conferences and shows.

1.3.2.9 The Administrative Support Assistant provides administrative support to NVLAP Program Managers and staff and performs various office duties, such as mail distribution, word processing, preparation of purchase orders and training requests, phone coverage, and operation of certain office equipment.

1.3.2.10 The Information Support Clerk provides general office clerical support, including answering phones, fulfilling information requests, filing, and stocking office supplies, publications and forms.

1.3.3 Resources

1.3.3.1 NVLAP employs a sufficient number of personnel having the necessary education, training, technical knowledge, and experience for handling the type, range, and volume of work performed (see Section 18.2, *Training of NVLAP Staff*).

1.3.3.2 The resource requirements for the management of the quality system, the performance of work, and in-house verification activities, including internal quality audits, are explicitly defined in the QSM, the *NVLAP Administrative Procedures Manual*, and the *NVLAP Operating Instructions Manual*.

1.3.4 Management Representative

1.3.4.1 The Quality Manager, appointed by the NVLAP Chief, has the authority and responsibility for ensuring that the requirements for quality, as outlined in this manual, are effectively implemented and maintained at NVLAP. The Quality Manager has direct access to the NVLAP Chief as shown on the organizational chart in fig. 1.2.

1.3.4.2 Specifically, the Quality Manager is responsible for:

- implementing and monitoring the quality system as established by NVLAP management and defined in the quality manual and related quality documentation;
- ensuring that all personnel understand their importance in achieving the NVLAP Mission and Objectives for Quality;
- maintaining quality documentation, including the quality manual, and ensuring that all quality system documents have adequate controls in place;
- chairing the NVLAP Quality Committee and tracking and monitoring the status of all complaints and corrective and preventive actions;
- reporting on the performance of the quality system to NVLAP management for review and as a basis for improvement of the quality system;
- organizing and coordinating internal audits as needed, but at least once per year (see Sec. 17); and
- coordinating management reviews of the NVLAP quality system as needed, but at least twice per year (see Sec. 1.4).

1.3.5 Quality Committee

1.3.5.1 The NVLAP Quality Committee consists of the Quality Manager as chair, and staff selected by the Management Committee. As stated in the objectives for quality, a team approach is a key strategy to foster continuous quality improvement through employee involvement; therefore, committee members are selected by NVLAP management from a cross-section of NVLAP positions. (See Appendix C.)

1.3.5.2 The Quality Committee is responsible for making recommendations concerning the implementation, review, and updating of the quality system to the NVLAP Chief, and for monitoring the implementation of approved actions.

1.3.5.3 Information on committee actions are circulated to and understood by all NVLAP staff, assessors, and other persons affected by those actions; feedback received from the affected parties is reviewed and considered by the committee in a timely manner.

1.4 MANAGEMENT REVIEW

1.4.1 The NVLAP quality management system is formally reviewed by the Management Committee at least twice per year. The review shall be conducted as an activity separate from the internal audit.

Informal management reviews are conducted frequently at NVLAP through the inclusion of quality as a standing agenda item at every Management Committee meeting. Minutes of Management Committee meetings are distributed to all NVLAP staff.

1.4.2 Management Review is coordinated by the Quality Manager and addresses the following agenda items:

1.4.2.1 assessment of the effectiveness of the quality system in achieving NVLAP's quality policy and quality objectives;

1.4.2.2 assessment of likely future requirements to ensure that the system will remain suitable and effective; and

1.4.2.3 review of the evidence from internal audits, corrective and preventive actions, follow-up assessment of the effectiveness of such actions, laboratory complaints, reported service problems, and concessions granted.

1.4.3 The Quality Manager:

1.4.3.1 reviews material provided by each staff person having done the review of the quality system in his or her area of responsibility;

1.4.3.2 assembles a written report addressing the above agenda items and the conclusions reached;

1.4.3.3 submits the report to the NVLAP Chief;

1.4.3.4 issues corrective and preventive actions in consultation with the Quality Committee, and follows up on the effectiveness of corrective and preventive actions taken; and

1.4.3.5 files and maintains records of the management review for a period of 5 years. The records shall show evidence of how the review was conducted, who was involved, what factors were considered, what conclusions were reached, and what actions were taken.

1.5 ACCEPTANCE OF ACCREDITATION

1.5.1 In support of its Mission Statement and Objectives for Quality, NVLAP Program Managers and staff promote the acceptance of NVLAP certificates of accreditation, scopes of accreditation, and accredited laboratory test and calibration reports by U.S. and foreign governmental agencies, accreditation bodies, users of laboratories, and public and private sector organizations, nationally and internationally.

1.5.2 NIST enters into agreements with other federal agencies, state and local governments, agencies of foreign countries, domestic laboratory accreditation programs, and other nonprofit organizations for the purposes of:

1.5.2.1 meeting the regulatory needs of governments;

1.5.2.2 meeting the quality and technical needs of laboratory operators and users;

1.5.2.3 reducing the development and operation of redundant accreditation programs and the associated costs of multiple assessments and administration;

1.5.2.4 facilitating exports of goods to a specific country or region with which significant trade links are maintained;

1.5.2.5 facilitating acceptance of a specific commodity in a specific country or region as requested by laboratories, manufacturers, and/or exporters;

1.5.2.6 providing assistance to accredited laboratories and users of test data in all countries participating in an agreement; and/or

1.5.2.7 developing closer technological ties with a particular country as part of overall government policy.

1.5.3 Such agreements may take the form of Memoranda of Understanding (MOUs) (see procedures contained in Sec. 8.05.12 of the *NIST Administrative Manual*), Mutual Recognition Agreements (MRAs), or Multilateral Agreements (MLAs).

1.5.4 The NVLAP Chief, as an agent of NIST, is responsible for the execution of agreements with other agencies and organizations, both domestic and international. Recognition of accreditations granted by other accreditation systems is based upon the determination of equivalence of programs.

1.5.5 Approval of agreements is required from OSS, TS, NIST Office of International and Academic Affairs, NIST Deputy Chief Counsel, and U.S. Department of State, as

appropriate. Agreements must be signed by the Deputy Director of NIST (or a designee) or higher.

1.5.6 The NVLAP Chief assigns and provides the resources necessary for NVLAP staff to participate in the plenary meetings, working groups, and committees of the International Laboratory Accreditation Conference (ILAC); the European Cooperation for Accreditation of Laboratories (EAL); Asia-Pacific Laboratory Accreditation Cooperation (APLAC); North American Calibration Cooperation (NACC); ISO Council Committee on Conformity Assessment (ISO-CASCO); and other relevant bodies in order to exchange experience with other laboratory accreditation practitioners.

1.6 REFERENCING NVLAP ACCREDITATION

1.6.1 The term *NVLAP* and the NVLAP logo are federally registered trademarks of the National Institute of Standards and Technology and the federal government, who retain exclusive rights therein. Permission to use the term and/or the logo is granted to NVLAP-accredited laboratories for limited purposes. NIST reserves the right to control the quality of the use of the term *NVLAP* and of the logo itself.

1.6.2 Procedures for referencing NVLAP accreditation are contained in Sec. 285.8 of NIST Handbook 150. Other NVLAP documents may also apply.

2.0 QUALITY SYSTEM

Section 2 of the QSM addresses the requirements of clause 4.2 (Quality System) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

2.1 GENERAL

2.1.1 NVLAP maintains a documented quality system as a means to ensure that all services conform to specified requirements. ISO 8402:1994, *Quality Management and Quality Assurance—Vocabulary*, defines *quality system* as "the organizational structure, procedures, processes, and resources needed to implement quality management." Figure 2.1 illustrates the structure of the documented quality system at NVLAP.

2.1.2 NISTIR 5630, *NVLAP Comparison of NIST Handbook 150 with ISO/IEC Guide 58:1993*, provides a cross-reference table which identifies the location of Guide 58 requirements in NVLAP's quality system.

2.2 QUALITY SYSTEM DOCUMENTATION

The following four levels of documentation are utilized and maintained to ensure adequate control and to meet the requirements of the ISO 9001:1994/Q9001 Standard, and the requirements for accreditation bodies contained in ISO/IEC Guide 58.

2.2.1 Quality System Manual (QSM)

2.2.1.1 The QSM describes NVLAP's quality policy and the general structure and methods for maintaining the quality management system. The manual references the related quality system procedures that must be followed to meet the specified policies and approaches.

2.2.1.2 The manual is a *controlled document*, meaning that copies are numbered and assigned to holders, and that a method is employed to confirm receipt of changes to the manual by the holders (as defined in Sec. 5.2.7).

2.2.1.3 The manual has four primary functions:

- to formalize commitment of NVLAP management to principles and practices of quality assurance and to establish an environment in which NVLAP staff actively and confidently support and implement quality assurance activities in accordance with written performance standards;
- to provide a resource document for NVLAP personnel which defines the NVLAP processes, responsibilities, authorities, and

the obligations and duties of each NVLAP position/function which affects quality;

- to provide a methodology for auditors to objectively evaluate NVLAP compliance with its own internal standards of performance;

- to inform participating laboratories, assessors, contractors, NIST colleagues, and the concerned public, about NVLAP organization and policies and the process for assuring continuance of a high quality program.

2.2.2 Quality System Procedures

NVLAP maintains documented quality system procedures to meet its need to effectively manage and control the quality system. The following documents constitute NVLAP's collective body of quality system procedures:

2.2.2.1 NIST Handbook 150, *NVLAP Procedures and General Requirements*, sets forth the procedures and general requirements under which NVLAP operates as an unbiased third party to accredit both calibration and testing laboratories (see Appendix D). Section 285.33 of the handbook, *Criteria for accreditation*, includes all of the requirements specified by ISO/IEC Guide 25, *General requirements for the competence of calibration and testing laboratories*, and by ANSI/NCSL Z540-1-1994, *Calibration Laboratories and Measuring and Test Equipment—General Requirements*.

2.2.2.2 The *NVLAP Administrative Procedures Manual* (APM) supplements NIST Handbook 150 and describes the procedures which specify who does what, when it is done, and what documentation is used to verify that the quality activity was executed as required (see Appendix E). The steps followed in establishing, implementing, maintaining and controlling documented quality system procedures are defined in the APM.

2.2.2.3 The *NIST Administrative Manual*, published by Directives Management, NIST Management and Organization Division, is the official medium for formal publication of NIST's policies, procedures, instructions, and definitions of organizational structure, function, and responsibilities (see Appendix F). Policies and procedures in the *NIST Administrative Manual* are applicable to all NIST employees unless stated otherwise.

NVLAP's copy of the manual is maintained complete and up-to-date by the NVLAP Secretary. Revisions to the manual are sent out to holders with a transmittal sheet which highlights the content changes. Pages superseded by revisions are discarded as indicated on the transmittal sheet. A checklist showing the correct pages which should appear in the manual is issued annually.

Many sections of the *NIST Administrative Manual* are also accessible on the NIST internal website, http://www-i.nist.gov/admin/mo/adman/contents.htm.

2.2.3 Quality System Instructions

The NVLAP *Operating Instructions Manual* (OIM) describes the work instructions used by NVLAP to detail how particular tasks are to be performed where the absence of such instructions would adversely affect quality. The steps followed in establishing, implementing, maintaining, and controlling operating instructions are defined in the APM.

2.2.4 Records, Forms and Reports

Records, forms and reports are used by NVLAP to provide assurance and evidence that the required quality of service was achieved, and that NVLAP's quality system has been implemented correctly. Some examples of the many documents that fall into this category are NIS database records, application forms, checklists, complaint records, assessor questionnaires, contents of laboratory folders, and NIS reports. All records, forms, and reports are generated, handled and filed in accordance with NVLAP's document control system (Section 5) and APM 03.07, *Records Management*.

2.3 QUALITY PLANNING

2.3.1 Quality planning at NVLAP is comprised of the procedures and operating instructions used to provide its service—accreditation. NVLAP gives consideration to the following activities, as appropriate, in meeting the requirements for service:

2.3.1.1 the preparation of quality plans (defined in ISO 8402:1994 as "a document setting out the specific quality practices, resources, and sequence of activities relevant to a particular product, project or contract"); a quality plan may be in the form of a reference to the appropriate documented procedures (e.g., sections of NIST Handbook 150 and/or the QSM); in NVLAP, quality planning may also be interpreted to mean the preparation of program development plans which are specific to a particular laboratory accreditation program (LAP) (see NIST Handbook 150, Subpart B);

2.3.1.2 the identification and acquisition of the technical expertise, knowledge, and resources necessary to achieve the required LAP quality;

2.3.1.3 ensuring the compatibility of the design, development, implementation, and servicing of a given LAP, and the applicable documentation;

2.3.1.4 the updating as necessary of quality control and inspection techniques, e.g., enhancements to the NVLAP Information System (NIS);

2.3.1.5 the identification of suitable verification at appropriate stages in the LAP development and accreditation processes;

2.3.1.6 the clarification of standards of acceptability for all features and requirements, including those which contain a subjective element, through the development and publishing of LAP-specific handbooks, checklists, and other guidance; and

2.3.1.7 the identification and preparation of quality records (see Section 16).

2.3.2 All NVLAP employees have the responsibility to execute and adhere to the requirements of the defined quality system.

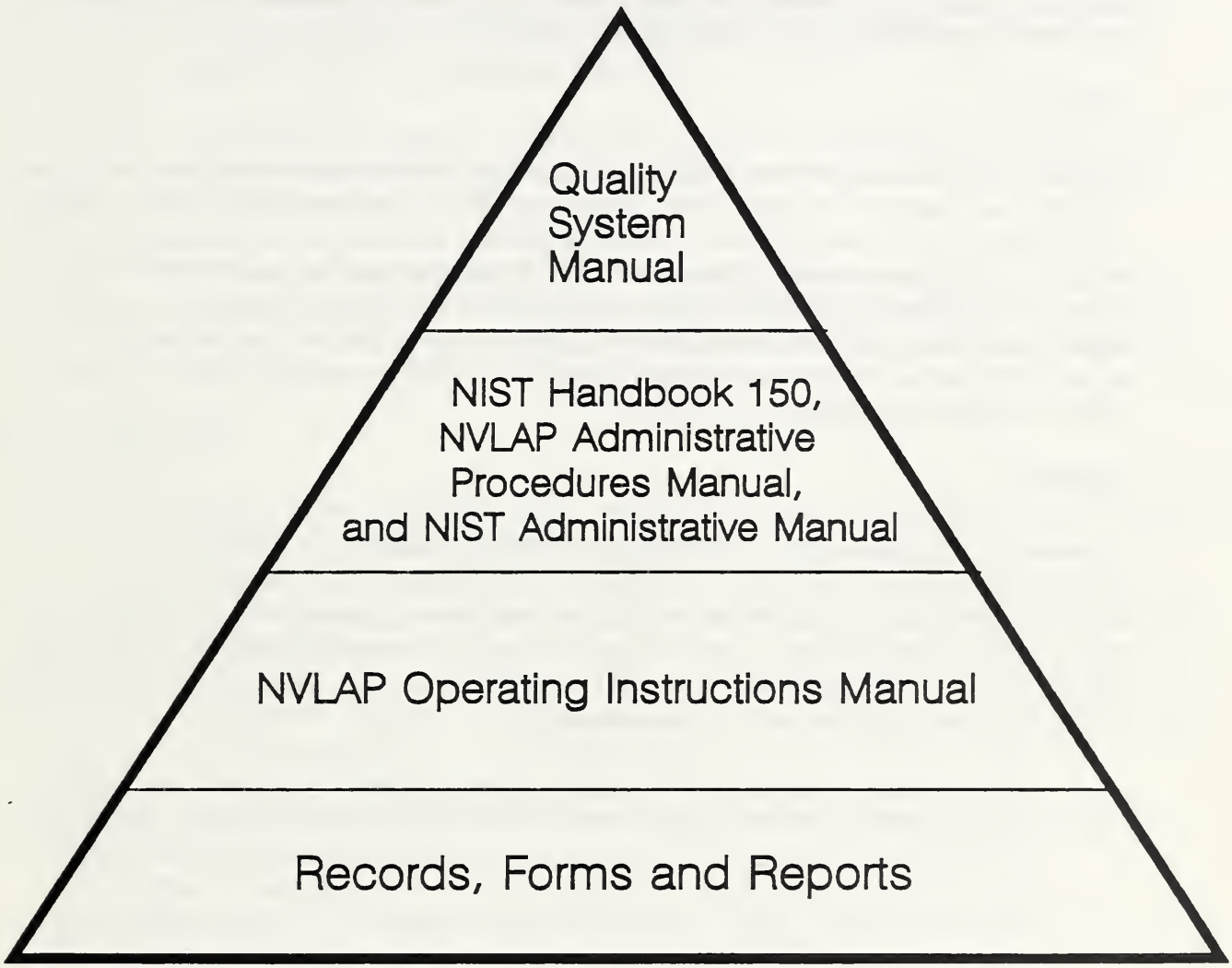
Quality System Manual
NIST Handbook 150, NVLAP Administrative Procedures Manual, and NIST Administrative Manual
NVLAP Operating Instructions Manual
Records, Forms and Reports

Figure 2.1. NVLAP Quality System Documentation

3.0 CONTRACT REVIEW

Section 3 of the QSM addresses the requirements of clause 4.3 (Contract Review) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

3.1 GENERAL

ISO 9001:1994 defines the term *contract* as an accepted order or agreed requirements between a supplier and customer transmitted by any means. NVLAP (as the supplier) does not enter into a formal, written contract with a purchaser (either a laboratory or a requestor of a LAP) to supply accreditation services. However, NVLAP provides services as described in the U.S. Code of Federal Regulations (CFR), Title 15, Part 285, *NVLAP Procedures and General Requirements*, and gives this information to applicant laboratories and other requestors. To request accreditation or the development of a LAP, a laboratory or other organization must follow the procedures outlined in the CFR.

3.2 REVIEW

A laboratory's application for accreditation, in which the laboratory's Authorized Representative agrees in writing to meet specified conditions for accreditation, may be considered an "order" for accreditation. In this sense, the requirements for contract review (which apply to simple orders as well as detailed written contracts) are fulfilled through the following activities (in accordance with NIST Handbook 150, Sec. 285.21(a) and (b) and OIM 21.01, *Processing Applications for Accreditation*).

3.2.1 Each application received by NVLAP is reviewed by the Management and Program Assistant (MPA) for completeness in accordance with NVLAP operating instructions. The review includes checking to ensure that payment has been calculated correctly, that the application is properly identified (see Sec. 8.2), and that the Authorized Representative has signed the Conditions for Accreditation. An application is not processed until all parts of the application have been satisfactorily completed and payment has been received.

3.2.2 The Program Manager reviews the test methods selected on the application and any problem areas identified by the MPA. The Program Manager ensures that the test methods have been selected on the application in a clear and unambiguous manner. If there are any ambiguities, the Program Manager (or MPA) contacts the laboratory and resolves them before proceeding with the next step of the accreditation process.

3.2.3 NVLAP will not accept any application for accreditation for which it cannot provide full and satisfactory service.

3.2.4 It is NVLAP's policy to safeguard the confidentiality of all information contained on applications for accreditation.

3.3 AMENDMENTS

3.3.1 NVLAP procedures require that an accredited laboratory inform NVLAP of any changes that affect the laboratory's scope of accredited activities or capability to perform the test or calibrations for which it is accredited.

3.3.2 The Program Manager is responsible for coordinating additions or deletions to an application or scope of accreditation with the laboratory and notifying all affected NVLAP personnel of relevant changes.

3.3.3 In the event that a laboratory requests the addition of test or calibration methods to its scope of accreditation for an given LAP and the requested methods are currently not part of that LAP, the procedures in NIST Handbook 150, Sec. 285.18, *Adding to or modifying an established LAP*, are followed.

3.4 RECORDS

3.4.1 The list of test and/or calibration methods selected for accreditation by each applicant laboratory is recorded electronically in the NIS.

3.4.2 The hard copy, signed application forms are filed in each laboratory's file folder by renewal year.

3.4.3 Requests for changes or additions to a laboratory's scope of accreditation are filed in the laboratory's file folder by renewal year.

3.4.4 Retention periods for the above records are specified in Section 8.5, *Traceability*.

4.0 DESIGN CONTROL

Section 4 of the QSM addresses the requirements of clauses 4.4.1 (General), 4.4.2 (Design and Development Planning), 4.4.3 (Organizational and Technical Interfaces), 4.4.4 (Design Input), 4.4.5 (Design Review), 4.4.6 (Design Output), 4.4.7 (Design Verification), 4.4.8 (Design Validation), and 4.4.9 (Design Changes), in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

4.1 GENERAL

NVLAP maintains documented procedures to control and verify the design of its LAPs. The procedures for establishing and modifying a LAP are published in NIST Handbook 150, Sections 285.11 through 285.18. Procedures for obtaining/documenting public comments are contained in the Administrative Procedure Act and related documentation.

4.2 DESIGN AND DEVELOPMENT PLANNING

4.2.1 The Director of NIST has delegated to the Chief of NVLAP the responsibility for the establishment of LAPs (see Appendix I).

4.2.2 The requestor of a LAP submits the initial requirements and preliminary design for the LAP to the Chief of NVLAP.

4.2.3 If the Chief determines that a need has been demonstrated for a LAP and if resources are available to develop the LAP, NVLAP notifies interested persons of the decision to proceed with the design and development of the LAP.

4.2.4 The Chief assigns the new LAP to a NVLAP Program Manager.

4.2.5 The assigned Program Manager establishes a new program file (LAP folder) and defines a design and development plan in consultation with other NVLAP managers, NIST technical units, the private sector, and other government agencies.

4.3 ORGANIZATIONAL AND TECHNICAL INTERFACES

The assigned Program Manager is responsible for identifying the organizational and technical interfaces between different groups which provide input information to the design process. This responsibility includes:

4.3.1 ensuring that the necessary information is documented, transmitted, and reviewed; e.g., informing the affected calibration or testing community of any planned workshop;

4.3.2 communicating and consulting with appropriate officials within those federal agencies that may have an interest in and may be affected by the establishment of the LAP; and

4.3.3 arranging for the participation of relevant and impartial persons, who possess the necessary technical competence, in the interpretation of NVLAP requirements for a specific test, calibration, or type of test or calibration.

4.4 DESIGN INPUT

4.4.1 Design input requirements, including applicable statutory and regulatory requirements, are identified, specified, documented and reviewed by the assigned Program Manager for adequacy.

4.4.2 The Program Manager is responsible for arranging public workshops (or other suitable means) to identify and review the design input (technical requirements) relating to the establishment of the LAP. Public workshops are part of the NVLAP process of assuring that LAPs are of high technical quality, responsive to the technical needs of the laboratory community, and are relevant to the needs of those affected by accreditation. The Program Manager may also solicit input from persons having expertise in the field of accreditation, such as engineers, scientists, consultants, and college professors.

4.4.3 LAP design input requirements are developed only after incomplete, ambiguous, or conflicting requirements have been resolved with those responsible for their definition and specification.

4.5 DESIGN OUTPUT

4.5.1 The assigned Program Manager is responsible for ensuring that design output (technical requirements) is documented and expressed in terms that can be verified against design input and validated.

4.5.2 Design output includes program handbooks, specific operations checklists, application forms and test method selection lists, critical elements, proficiency testing requirements, and other LAP-specific documents. The design output shall:

4.5.2.1 meet the design input requirements;

4.5.2.2 contain or reference LAP acceptance criteria;

4.5.2.3 conform to appropriate regulatory requirements whether or not these have been stated in the input information; and

4.5.2.4 identify those characteristics of the design that are critical to sound accreditation decisions.

4.6 DESIGN REVIEW

Reviews of a LAP design are coordinated by the assigned Program Manager and include representatives of all functions concerned with the design stage being reviewed. These may take the form of additional workshops or meetings and phone calls with input providers and specialists. Records of all reviews, formal and informal, are maintained in the LAP folder. [Note: Records may not be available for older programs.]

4.7 DESIGN VERIFICATION AND VALIDATION

The assigned Program Manager is responsible for ensuring that design output for a LAP meets the design input requirements prior to announcing the establishment of the LAP in the *Federal Register*. This is accomplished through the following design control measures:

4.7.1 holding and recording design reviews (see Sec. 4.6);

4.7.2 comparing the design for a new LAP with that of existing LAPs;

4.7.3 distributing output documents to the providers of input (e.g., workshop attendees and technical experts) and soliciting their comments; and

4.7.4 reviewing and incorporating comments into design output documents as appropriate.

4.8 DESIGN CHANGES

4.8.1 Procedures for the identification, review, and approval of changes and modifications to a LAP are contained in NIST Handbook 150, Sec. 285.18, "Adding to or modifying an established LAP."

4.8.2 The assigned Program Manager is responsible for analyzing, processing and implementing requested additions and modifications to a LAP.

4.8.3 Documentation relating to requests for additions or modifications is filed in the LAP folder.

4.8.4 The Program Manager recommends design changes to the NVLAP Chief, who in turn, gives final approval of the proposed additions or modifications.

4.8.5 The Program Manager notifies NVLAP staff, laboratories, assessors, and other interested parties of the design changes in accordance with Section 5.3.

5.0 DOCUMENT AND DATA CONTROL

Section 5 of the QSM addresses the requirements of clause 4.5 (Document and Data Control) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

5.1 GENERAL

NVLAP maintains procedures to identify and control documents and data in all media that relate to the requirements of ISO 9001:1994 and ANSI/ASQC Q9001-1994, including documents and data supplied by the laboratories or other sources and used to provide accreditation services. In addition, Subchapter 4.09, "NIST Technical Communications Program," of the *NIST Administrative Manual* sets forth policies and procedures and defines responsibilities that apply to the communication of NIST technical program results.

5.2 DOCUMENT APPROVAL AND ISSUE

5.2.1 The NVLAP Chief is responsible for the technical and editorial quality of all documents prepared by NVLAP staff members. All NVLAP documents to be published must be approved by the NVLAP Chief prior to printing and distribution.

5.2.2 If a manuscript, paper, or report is intended for distribution to the public, the Washington Editorial Review Board (WERB) must review and approve the document before it is submitted for publication (see *NIST Administrative Manual*, 4.09 Appendix H).

5.2.3 Information collection at NVLAP is subject to the requirements of the federal Paperwork Reduction Act. All NVLAP application forms must be reviewed and approved by the Office of Management and Budget (OMB) at prescribed intervals. The General Application must bear the OMB approval number and approval expiration date.

5.2.4 All information published on the NVLAP home page on the Internet must be reviewed and approved by the Information Systems Committee prior to submission to the webmaster.

5.2.5 Each Program Manager is responsible for:

5.2.5.1 initiating, reviewing and approving documents which are specific to his/her assigned LAP(s);

5.2.5.2 ensuring that such documents are appropriately identified during the various stages of production (e.g., stamped "DRAFT"); and

5.2.5.3 ensuring that all documents to be published are free of routine errors and requirements for essential revisions before submittal to WERB.

5.2.6 The Business Manager is responsible for ensuring that:

5.2.6.1 master lists of NVLAP-issued documents (i.e., handbooks, applications, checklists, and NIST Interagency or Internal Reports) are maintained to identify their current revision dates and preclude the use of obsolete documents;

5.2.6.2 NVLAP-issued documents (i.e., handbooks, applications, checklists, and NIST Interagency or Internal Reports) are identified by a unique title or number and revision date and are saved in write-protected computer files;

5.2.6.3 all NVLAP publications are reviewed and approved by the appropriate levels of authority prior to printing, distribution, and use;

5.2.6.4 the necessary interfaces with the NIST Publications and Productions Division occur to ensure conformance to the Department of Commerce *Publishing and Printing Manual*, the *U.S. Government Printing Office Style Manual*, and to NIST policies and procedures;

5.2.6.5 pertinent issues of appropriate documents are available to all NVLAP staff and participating laboratories, and at all locations where operations essential to the effective functioning of the quality system are performed;

5.2.6.6 obsolete documents are promptly removed from all points of use within NVLAP; and

5.2.6.7 one copy of each obsolete document is properly identified and retained in a permanent archive file.

5.2.7 **Quality System Documents**

The NVLAP QSM, APM, and OIM (see Sec. 2.2) are subject to the NVLAP document control policies outlined above. In addition, the Quality Manager is responsible for ensuring that these documents:

5.2.7.1 are reviewed and approved by the responsible managers and/or technical group prior to issuance, have provisions for review and approval signatures, and have a means for indicating the document revision number and date;

5.2.7.2 are numbered and assigned to an individual or area of use (see list of QSM holders in Appendix G);

5.2.7.3 are controlled by means of a register which indicates the document/copy number, the names and locations of all holders, and the current revision status of the document; and

5.2.7.4 are kept up-to-date through revisions which are issued to holders. Holders acknowledge receipt of changes by returning signed confirmation slips to the NVLAP Quality Manager (see Appendix H).

5.3 DOCUMENT CHANGES/MODIFICATIONS

Document changes and modifications are made, reviewed, approved, identified, and communicated at NVLAP based on the following criteria:

5.3.1 Documents changes and modifications are reviewed and approved by the same personnel who performed the original review and approval, unless specifically designated otherwise. In those situations, the Business Manager, who is responsible for records management, ensures that the designated personnel have access to all pertinent background information upon which to base an accurate and consistent review and approval.

5.3.2 If a document that is intended for distribution to the public is changed substantially after WERB approval, the Chairperson of WERB must be informed and given an opportunity to determine the need, if any, for additional review and approval.

5.3.3 Where applicable, the nature of the changes are identified in the document or the appropriate attachments.

5.3.4 Each Program Manager, in consultation with the Business Manager, is responsible for issuing revised documents specific to his/her assigned program area to NVLAP staff, participating laboratories, assessors, contractors, and other interested parties.

6.0 PURCHASING

Section 6 of the QSM addresses the requirements of clauses 4.6.1 (General), 4.6.2 (Evaluation of Vendors), 4.6.3 (Purchasing Data), and 4.6.4 (Verification of Purchased Product) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

6.1 GENERAL

6.1.1 In the federal government, the term *purchasing* is typically used to refer to the acquisition of goods and services under a specific dollar limitation through the use of simplified small purchase procedures prescribed in the Federal Acquisition Regulation (FAR). It may also be used to describe the techniques of acquiring goods and services from a number of established sources. The term *contracting* means purchasing, renting, leasing, or otherwise obtaining supplies or services from non-federal sources.

6.1.2 All procurement of property and/or services is made in strict accordance with applicable laws, regulations, Comptroller General decisions, and Department of Commerce policies, procedures, and instructions (see *NIST Administrative Manual*, Subchapter 2.03, "Procurement").

6.1.3 NVLAP Program Managers have procurement authority for small purchases and are responsible for ensuring that subcontracted services from assessors conform to specified requirements.

6.1.4 For a specific contract for services (e.g., proficiency testing or ADP), the Contracting Officer's Technical Representative (COTR), who may or may not be a Program Manager, is responsible for ensuring that subcontracted services conform to specified requirements.

6.2 EVALUATION OF VENDORS

6.2.1 Assessors

Each Program Manager is responsible for:

6.2.1.1 qualifying assessors on the basis of defined criteria (see APM 22.01, *Assessors—Recruitment, Selection, and Training*) related to their ability to meet NVLAP's requirements for quality, cost, and delivery;

6.2.1.2 establishing a list of assessors approved to perform on-site assessments and other evaluative functions for that Program Manager's assigned LAP(s) (the list of assessors is maintained in the NIS by the Program Manager and the Management and Program Assistant);

6.2.1.3 ensuring that all assessors have signed an Assessor Declaration by which they commit themselves to comply with NVLAP's rules, including those relating to confidentiality and conflicts of interest; and

6.2.1.4 monitoring the performance of assessors, reviewing their capability versus NVLAP's requirements, and conducting evaluations through the use of Assessor Questionnaires and other means.

6.2.2 Other Subcontractors

6.2.2.1 NVLAP may use a subcontractor to perform services in support of NVLAP proficiency testing programs, such as the acquisition, manufacture and characterization of proficiency testing materials and the conducting of proficiency testing under NVLAP guidance.

6.2.2.2 NVLAP may also use subcontractors to design, develop, test, implement, document, and maintain information systems and associated hardware, and to perform other special services as required.

6.2.2.3 The initiator of a Request for Contract (in NVLAP, this person is normally appointed as the COTR for the contract) is responsible for the development of the technical evaluation criteria to be used in selecting a subcontractor. A written source selection plan spells out how the process of subcontractor selection will be conducted, including details on how NIST/NVLAP will evaluate proposals for a particular contract. Contracts are awarded in conformance with U.S. government regulations contained in the FAR.

6.2.2.4 In the event that NVLAP subcontracts the assessment of a laboratory to another body, then NVLAP takes full responsibility for the assessment made on its behalf. NVLAP ensures that any body to which assessment has been delegated is competent and complies with the applicable provisions of this manual and NIST Handbook 150.

6.3 PURCHASING DATA

6.3.1 The precise description of the technical requirements for a material, product, or service, that includes the criteria for determining whether these requirements are met, are defined as a *specification* by the FAR. The FAR sets forth a system of federal specifications which are mandatory for use. The requirements expressed may be called various names; (i.e., statement or work, purchase description, etc.) and the terms are used virtually interchangeably. The FAR (FAR 10.004(b)(1)) provides guidance on the content of purchase descriptions, such as type and grade of material, common nomenclature, dimensions, etc.

6.3.2 The Program Manager reviews and approves purchase orders and Blanket Purchase Agreements (BPAs) for assessor services (the procurement vehicles most often used by NVLAP to procure the services of assessors) for adequacy of specified requirements prior to release.

6.3.3 The appointed COTR reviews and approves non-BPA contract documents for adequacy of technical requirements. The appointed NIST Contracting Officer reviews and approves the contract documents for adequacy of other specified requirements (non-technical) prior to contract solicitation, offer, and award.

6.4 VERIFICATION OF PURCHASED SERVICES

6.4.1 Supplier Verification

NVLAP reserves the right to verify the competence of subcontractors through on-site inspection or other means as applicable.

6.4.2 Customer Verification

NVLAP defines its customers as testing and calibration laboratories in the private and public sectors, whereas regulatory agencies, purchasing authorities, consumers, and industry are considered NVLAP stakeholders; therefore, the requirements of clause 4.6.4.2 of ISO 9001:1994 and ANSI/ASQC Q9001-1994, concerning customer verification of subcontracted product, are inappropriate for the NVLAP process and do not apply.

6.5 PURCHASING RECORDS

6.5.1 Records pertaining to the evaluation of assessors and procurement of assessor services are maintained in the assessor files (hard copy), BPA files (hard copy), and NIS. APM 22.01 specifies the complete list of assessor records to be maintained.

6.5.2 Contract records (non-BPA) are maintained by the COTR and include as a minimum the COTR appointment memorandum and acknowledgment, the contract and any modifications, all contract correspondence, records of COTR inspections, records of conversations with the contractor, and copies of invoices/vouchers.

7.0 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

▸ The requirements of clause 4.7 (Control of Customer-Supplied Product) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994, do not apply to NVLAP.

8.0 PRODUCT IDENTIFICATION AND TRACEABILITY

Section 8 of the QSM addresses the requirements of clause 4.8 (Product Identification and Traceability) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

8.1 GENERAL

8.1.1 NVLAP establishes and maintains procedures for identifying documentation from its receipt or generation throughout the LAP-development and accreditation processes.

8.1.2 Identification of laboratory-related documentation and correspondence is maintained and controlled through the issuance of a NVLAP Lab Code to a laboratory immediately upon application. The NVLAP Lab Code is a unique alphanumeric identifier used for identification, recordkeeping, and database management.

8.1.3 NVLAP conforms to the requirements for the identification of correspondence at NIST contained in Subchapter 4.05, Appendix A, of the *NIST Administrative Manual*. Specific procedures for the preparation and identification of controlled correspondence are contained in this subchapter and in *The Executive Secretariat Manual for the Secretary's Procedures* (issued under the authority of DAO 214-9).

8.2 IDENTIFICATION OF INCOMING MATERIALS

8.2.1 The Administrative Support Assistant ensures that all incoming correspondence and documents are date-stamped and labeled appropriately (e.g., marked with the NVLAP Lab Code) in accordance with the operating instruction, *Processing Incoming/Outgoing Mail* (OIM 03.03).

8.2.2 The Management and Program Assistant assigns a NVLAP Lab Code to an initial applicant laboratory in accordance with the operating instruction, *Setting Up An Initial Accreditation* (OIM 21.02).

8.2.3 The Management and Program Assistant ensures that the Lab Code is marked on each sheet of an application (initial or renewal) upon receipt.

8.2.4 The receipt of certain incoming laboratory documentation, such as on-site assessment reports and deficiency responses, is recorded in the NIS by the Management and Program Assistant.

8.2.5 IDENTIFICATION OF IN-PROCESS MATERIALS

8.2.6 All NVLAP personnel are responsible for ensuring that the NVLAP Lab Code and date are marked on any laboratory-related documents they generate which pertain to processing a laboratory's application for accreditation. Examples of such documents are:

8.2.6.1 phone messages and records of phone conversations;

8.2.6.2 outgoing correspondence;

8.2.6.3 memoranda to the file;

8.2.6.4 proficiency testing reports; and

8.2.6.5 panel review documents.

8.2.7 The Business Manager is responsible for ensuring that the title and revision date appear on all NVLAP-generated forms, handbooks, brochures, and other published materials.

8.2.8 Program Managers are responsible for ensuring that in-process materials (e.g., on-site assessment reports, laboratory quality manuals, proficiency testing results, workshop minutes, etc.) are clearly identified and stored in the appropriate laboratory or LAP folders when not in use.

8.3 IDENTIFICATION OF FINISHED PRODUCTS

8.3.1 The Program Manager is responsible for ensuring that each Certificate of Accreditation and Scope of Accreditation generated by NVLAP bears the correct NVLAP Lab Code, laboratory name, and accreditation expiration date.

8.3.2 The Business Manager is responsible for ensuring that all final publications bear the correct publication numbers, titles, and dates, and that directories of accredited laboratories are cross-referenced by NVLAP Lab Code.

8.4 TRACEABILITY

8.4.1 NVLAP maintains laboratory file folders which contain all records pertaining to the accreditation process, including applications, on-site assessment reports, deficiency response letters, and other correspondence. The laboratory file folders are identified and organized by NVLAP Lab Code in the NVLAP file room. Accreditation records for the most recent 5 years for active accreditations are maintained in NVLAP. Accreditation records older than 5 years are transferred to NIST storage (see 8.5.6).

8.4.2 When a laboratory has withdrawn from the NVLAP program or has allowed all of its accreditations to expire, the laboratory folder is removed to a holding area within NVLAP for inactive laboratories. Folders for inactive laboratories are maintained in NVLAP for a period of one year, after which they are retired to NIST records storage (see 8.5.6).

8.4.3 Current and historical data regarding laboratory accreditations are also kept in the NIS and are accessed by NVLAP Lab Code and accreditation ID number. Records are maintained in the NIS for an indefinite period of time.

8.4.4 NVLAP maintains LAP file folders which contain all records pertaining to the development of a specific LAP, including *Federal Register* and workshop notices, public comments, and correspondence with organizations and persons having an interest in the LAP. The file folders are identified and filed by LAP name. Folders for active LAPs are retained in NVLAP permanently; folders for discontinued LAPs are retained in NVLAP for 5 years.

8.4.5 Complete lists of records to be maintained in the hard copy laboratory folders and LAP folders are specified in the administrative procedure, APM 03.07, *Records Management*.

8.4.6 Upon expiration of the time period for retention of file folders in NVLAP, the folders are retired to the NIST Records Holding Area. Records retention schedules are applied immediately upon storage in accordance with the General Records Schedule of the National Archives and Records Administration.

[Note: See Section 16 of this manual, *Quality Records*, for additional information.]

9.0 PROCESS CONTROL

Section 9 of the QSM addresses the requirements of clause 4.9 (Process Control) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

9.1 GENERAL

9.1.1 The NVLAP managers involved in the processes which directly affect quality of service are responsible for ensuring that these processes are identified, planned, and executed under controlled conditions. Controlled conditions are defined to include the following:

9.1.1.1 compliance with the NVLAP QSM, NIST Handbook 150: *NVLAP Procedures and General Requirements*, ISO/IEC Guide 58, and applicable federal regulations;

9.1.1.2 documented operating procedures and work instructions;

9.1.1.3 monitoring and control of suitable process characteristics (e.g., accuracy, timeliness, and responsiveness) during the accreditation process and servicing of accreditations;

9.1.1.4 use of a suitable information management system (hardware and software) and system maintenance practices, including security and data backup practices, to ensure continuing process capability;

9.1.1.5 approval of various steps within the accreditation process, as designated in the appropriate procedures and instructions; and

9.1.1.6 written criteria for performance of NVLAP staff members (performance plans) and subcontractors (e.g., Assessor Questionnaires).

9.1.2 Procedures describing the stages of the NVLAP accreditation process are contained in NIST Handbook 150. Specifically, the processes leading to an accreditation that directly affect quality and that must be controlled include the following (see fig. 9.1):

9.1.2.1 receipt, review, and processing of applications for accreditation;

9.1.2.2 receipt and review of laboratory quality manuals;

9.1.2.3 arrangement and scheduling of on-site assessments;

9.1.2.4 management of the proficiency testing process, if required (see 9.1.4 below);

9.1.2.5 monitoring of resolution of deficiencies;

9.1.2.6 evaluation of assessment and proficiency testing results and preparation of a recommendation for accreditation; and

9.1.2.7 granting, denying, suspending, or revoking accreditation.

9.1.3 The use of controlled processes ensures that:

9.1.3.1 accreditation actions are uniform over time and among the laboratory population;

9.1.3.2 laboratory evaluations are conducted with no bias or favoritism; and

9.1.3.3 confidentiality is maintained in accordance with NIST Handbook 150, Sec. 285.7, and ISO/IEC Guide 58, 4.2.1(m).

9.1.4 The proficiency testing process at NVLAP is consistent with the provisions contained in ISO/IEC Guide 43:1997 (Parts 1 and 2), *Proficiency testing by interlaboratory comparisons—Part 1: Development and operation of proficiency testing schemes by laboratory accreditation bodies*, and *Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*, where applicable. Proficiency testing may be organized by NVLAP itself, its approved subcontractors (see Section 6.2.2), or an approved independent provider of proficiency testing services with whom the laboratories deal directly.

9.2 SPECIAL PROCESS CONTROL

9.2.1 In addition to regularly scheduled assessments, monitoring visits may be conducted by NVLAP at any time during the accreditation period either for cause or on a random selection basis, in accordance with NIST Handbook 150, Sec. 285.22(b)(6).

9.2.2 Procedures for monitoring visits are consistent with those for regularly scheduled assessments.

9.2.3 Records of assessment and monitoring activities are maintained in the laboratory folders in accordance with Section 8.5 of the QSM.

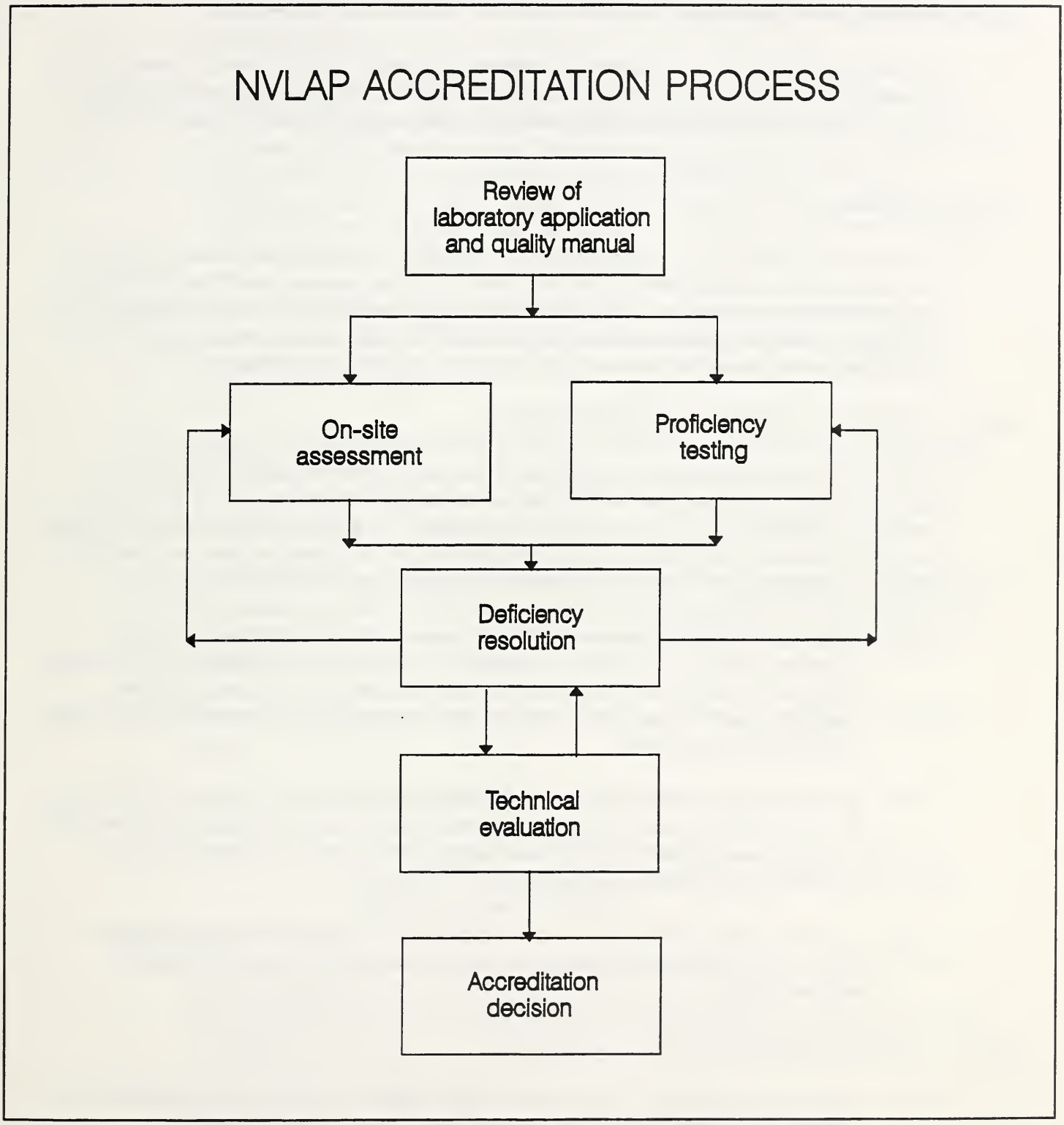

Figure 9.1. NVLAP Accreditation Process

10.0 INSPECTION AND TESTING

Section 10 of the QSM addresses the requirements of clause 4.10.1 (General), clauses 4.10.2 through 4.10.4 (Receiving, In-Process, and Final Inspection and Testing, respectively), and 4.10.5 (Inspection and Test Records) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

10.1 GENERAL

With respect to NVLAP, the terms *inspection and testing* are interpreted to mean verification that a stage of the accreditation process conforms to the requirements specified in NVLAP's quality system documentation. NVLAP establishes and maintains documented procedures and operating instructions which define the required activities and related records used to verify that all requirements are met prior to granting or renewal of an accreditation.

10.2 RECEIVING INSPECTION AND TESTING

In NVLAP, incoming product is the purchased services of subcontractors (assessors) to perform on-site assessments and other technical evaluations, which are part of the process leading to finished product—the accreditation decision. The Program Manager ensures that an accreditation is not processed until he/she verifies that the associated assessor services were performed satisfactorily. The requirements for inspection are fulfilled as follows.

10.2.1 In the case of an on-site assessment, the assessor submits to NVLAP a written assessment report. The Program Manager is responsible for checking and reviewing the report to ensure that the assessment was conducted in accordance with the specified requirements. This is also a means of monitoring assessor performance and identifying training needs.

10.2.2 In the case of a technical review panel, the Program Manager verifies the services of the participating assessor(s) through reviewing the Technical Evaluation Review Sheet, which an assessor uses to document whether or not a laboratory meets all of the technical requirements for accreditation.

10.2.3 An invoice for assessor services is not paid by NIST until the Program Manager approves the payment, indicating that the purchased services were performed satisfactorily.

10.3 IN-PROCESS INSPECTION AND TESTING

10.3.1 The Program Manager is responsible for ensuring that no stage of the accreditation process is completed until it has been verified as conforming to specified requirements. For example, a laboratory's initial request for accreditation will not be submitted to a technical review panel for an accreditation recommendation until the Program Manager reviews the laboratory records and determines that an on-site

assessment of the laboratory has been completed and deficiency response (if required) has been received.

10.3.2 Inspection of an in-process accreditation is done at designated checkpoints. Four reviews must be passed during the accreditation process for an initial accreditation to be granted: administrative review, Program Manager review, panel review, and final (Chief) review. [Note: Panel review is not a prerequisite for renewing an accreditation; however, a panel review is held subsequent to a laboratory's biennial on-site assessment. Failure to pass a review may result in a laboratory's suspension until the problem is resolved.]

10.3.3 Status records of each stage of an in-process accreditation are kept current and maintained in the NIS. Program Managers use this information to control the accreditation process and to identify laboratories that do not conform to NVLAP criteria.

10.3.4 Specific and detailed information relating to deficiencies is maintained in laboratory file folders.

10.4 FINAL INSPECTION AND TESTING

10.4.1 The NVLAP Chief is responsible for the final accreditation decision, as delegated by the Director of NIST. The Chief delegates the responsibility for this decision and subsequent final inspection of accreditation documents to the appropriate Program Manager.

10.4.2 The Program Manager is responsible for ensuring that no accreditation is granted until:

10.4.2.1 all identified deficiencies are resolved; and

10.4.2.2 all other requirements for accreditation have been satisfactorily fulfilled; e.g., payment of fees, administrative requirements, and successful technical evaluation.

10.4.3 The Program Manager checks to ensure that the test methods listed on the scope of accreditation match those for which the laboratory has applied, and that the accreditation documents otherwise conform to administrative procedures, before the documents are released.

10.5 INSPECTION AND TEST RECORDS

Records are established and maintained at NVLAP which identify the persons performing verification activities and the results of these activities. These records are retained in the NIS and laboratory file folders.

11.0 CONTROL OF INSPECTION, MEASURING AND TEST EQUIPMENT

The requirements of clause 4.11 (Inspection, Measuring, and Test Equipment) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994, do not apply to NVLAP. NVLAP uses no inspection, measuring, or test equipment (including test software) to demonstrate conformance of accreditation services to specified requirements (ISO/IEC Guide 58 and ISO 9001).

NVLAP does use measurement equipment, test artifacts and test software for proficiency test purposes when evaluating laboratory competency and compliance to ISO/IEC Guide 25. These proficiency tests are arranged and conducted in accordance with ISO/IEC Guides 43-1 and 43-2.

12.0 INSPECTION AND TEST STATUS

Section 12 of the QSM addresses the requirements of clause 4.12 (Inspection and Test Status) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

12.1 GENERAL

NVLAP identifies the inspection and test status of all stages of an accreditation by using forms, reports, and records (both NIS records and hard copy file records), which indicate the conformance or nonconformance of a laboratory accreditation with regard to the inspection and tests performed. The identification of this status is maintained throughout the accreditation process to ensure that an accreditation is only granted or renewed after the required inspections and tests have been passed.

Examples: (1) An initial accreditation is not granted to an applicant laboratory under the Bulk Asbestos Fiber Analysis LAP until the laboratory has passed PLM (polarized light microscopy) proficiency testing. Database records are maintained in the NIS which identify the proficiency testing status of a laboratory for a given round of testing (i.e., pass, fail, or did not participate).

(2) An application for accreditation is not processed until the application is checked and verified as being complete. In the NIS, the boxes for "Organizational Chart Received" and "Lab Description Received" must be checked and a date entered into the "Application Complete" field before subsequent activities, such as assessor assignment, may commence.

12.2 RESPONSIBILITIES

12.2.1 The Program Manager and Management and Program Assistant are responsible for the identification of the inspection and test status of accreditations in his/her assigned LAPs.

12.2.2 The Management and Program Assistant updates the status records in the NIS based on information from the Program Manager and from incoming reports and documents. Explanatory comments are entered into the NIS if an accreditation is placed on hold for any reason.

12.2.3 As stated in Sec. 10.4.1, the NVLAP Chief delegates the responsibility for the accreditation decision to the Program Manager. Once a decision is reached to grant accreditation to a laboratory, the Program Manager sets the Chief Review status in the NIS to "pass." Each Certificate of Accreditation and Scope of Accreditation issued by NVLAP bears the computer-generated signature of the NVLAP Chief to indicate "sign-off" of the accreditation (release of conforming product). The initials of the Program Manager in the Chief Review status field together with the accreditation documents serve as the final inspection and test status records.

12.2.4 NVLAP personnel who detect nonconformities in the accreditation process are responsible for following the policies and procedures addressed in Section 13 of this manual.

13.0 CONTROL OF NONCONFORMING PRODUCT

Section 13 of the QSM addresses the requirements of clause 4.13 (Control of Nonconforming Product) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

13.1 GENERAL

13.1.1 In NVLAP, a nonconforming product is any accreditation activity or result produced by an accreditation activity that does not conform to the requirements in NVLAP's quality system documentation. In this context, examples of nonconforming product may include incorrect entry of a pass/fail proficiency testing result into a laboratory's database record, or release of accreditation documents that contain errors.

13.1.2 NVLAP maintains documented procedures to ensure that accredited status is not inadvertently granted to a laboratory which does not meet NVLAP accreditation criteria.

13.1.3 Laboratories that have applied for accreditation, but are not accredited for any reason, are clearly identified by a non-accredited status code in the NIS (Suspended, Expired, Voluntarily Terminated, or New Lab) to prevent their inclusion in listings and directories of accredited laboratories. Supporting documentation that indicates current laboratory status is maintained in the laboratory folder.

13.1.4 A document pertaining to a laboratory's accreditation that contains an error is immediately segregated from conforming items upon identification of the error. If the document has not yet been issued to the laboratory, it is marked appropriately, such as "Cancelled," or shredded to prevent further use. If the document has already been issued and an error is detected, a copy is filed in the laboratory folder, together with the corrected copy, for the historical record.

13.2 RESPONSIBILITIES

13.2.1 Identification and reporting of nonconforming product is the duty and responsibility of each individual in NVLAP.

13.2.2 The manager of the operational area that produced the nonconforming product is responsible for the review and disposition of the product.

13.3 NONCONFORMING PRODUCT REVIEW AND DISPOSITION

13.3.1 If a nonconforming product has been detected, it is reworked until it meets the specified requirements. Since NVLAP does not grant accreditation to a laboratory until *all* accreditation criteria have been satisfied, the options for disposition of a nonconforming product do not include acceptance by concession; i.e., a condition less than the specified requirements.

13.3.2 The Program Manager inspects reworked product, such as a revised certificate or scope of accreditation, before release to the laboratory.

13.3.3 The laboratory is notified in writing by the Program Manager of any nonconformance which either substantially delayed its accreditation or led to an erroneous accreditation decision. A copy of such notification is filed in the laboratory folder.

13.3.4 Corrective action is taken when a nonconformity is detected: 1) first, an immediate positive action to satisfy the needs of the laboratory, and 2) an evaluation of the root cause of the nonconformity to determine any necessary longer-term corrective action to prevent recurrence of the problem (see Section 14).

14.0 CORRECTIVE AND PREVENTIVE ACTION

Section 14 of the QSM addresses the requirements of clause 4.14 (Corrective and Preventive Action) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

14.1 GENERAL

NVLAP establishes and maintains documented procedures for implementing both corrective and preventive action. These procedures specify actions for eliminating the cause of actual or potential quality system problems and related nonconformities to a degree commensurate with the magnitude of the problem, its potential outcome, and the level of risk involved.

14.2 RESPONSIBILITIES

14.2.1 The Quality Committee issues Corrective and Preventive Action Requests, reviews replies from responsible managers, and follows up on the effectiveness of actions taken.

14.2.2 The Quality Manager tracks the status of all action requests issued, ensures that timely reviews of responses are conducted by the Quality Committee, and maintains copies of action request records

14.2.3 All NVLAP employees have the authority and freedom to identify and document actual and potential quality system problems.

14.3 CORRECTIVE ACTION

Corrective action is directed at revising NVLAP's quality system, policies, procedures, and operating instructions in order to eliminate the root cause(s) of quality problems. NVLAP's Corrective Action Procedure (see APM 03.04) is used in the following situations:

14.3.1 to resolve quality system problems related to nonconformities found during internal or external audits;

14.3.2 to revise the quality systems, work processes, procedures and/or operating instructions to eliminate the cause of poor quality service, customer complaint, or internal quality failure; and

14.3.3 to resolve quality system problems found during the Management Review process.

14.4 PREVENTIVE ACTION

In addition to preventing problems through corrective action (by eliminating root causes of quality system failures), preventive action at NVLAP is directed at revising its quality system, policies, procedures, and operating instructions in order to eliminate the root cause(s) of

potential problems. NVLAP's Preventive Action Procedure (see APM 03.05) is used in the following situations:

14.4.1 to resolve weaknesses found and capitalize on "opportunities for improvement" identified during internal or external audits; and

14.4.2 to use information such as quality records, laboratory feedback, and Management Review reports to identify, analyze, and eliminate causes of potential nonconformities.

14.5 RECORDS

Corrective and preventive action request records are maintained by the Quality Manager for five (5) years.

15.0 HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

Section 15 of the QSM addresses the requirements of relevant clauses of 4.15 in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

15.1 GENERAL

NVLAP's "product" is accreditation, a service which cannot be handled, stored, packaged, preserved, or delivered in the sense of a tangible good. However, procedures and operating instructions are in place which address the storage, identification, and delivery of documentation relating to accreditation actions.

15.2 STORAGE

15.2.1 NVLAP maintains a file room that is secured by means of a cipher lock. Documents relating to laboratory accreditation are filed in laboratory folders organized by NVLAP Lab Code (see Sec. 8.5) in the NVLAP file room. Procedures are in place for the checking out of folders overnight by NVLAP personnel.

15.2.2 Backup tapes of information contained in the NIS are made nightly and archived and stored in a secure location.

15.3 PACKAGING

The requirements of clause 4.15.4 (Packaging) in ISO 9001:1994 and ANSI/ASQC Q9001-1994 include control of marking processes. All documents relating to accreditation are appropriately marked in a manner which allows for ready identification through all stages of processing as described in Section 8.0 of this manual. In particular, final accreditation documents (letters, certificates and scopes of accreditation) are marked with and identified by NVLAP Lab Code, as well as laboratory name and address, and accreditation expiration date. This identification is also consistent with the requirements of ISO/IEC Guide 58:1993, clause 6.6.1. If an accreditation document is reissued as a result of a revision, the revision date is also placed on the document.

15.4 DELIVERY

The Program Manager performs the final inspection of the accreditation documents before their release. If the documents are complete and correct, the Program Manager releases them to the to the Office Automation Clerk for delivery to the laboratory. The clerk maintains a log to record and track the mailing of accreditation documents, and mails the documents in accordance with operating instructions.

16.0 QUALITY RECORDS

Section 16 of the QSM addresses the requirements of clause 4.16 (Quality Records) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

16.1 GENERAL

16.1.1 A *record* is defined as a document which furnishes objective evidence of activities performed or results achieved (ISO 8402). A *quality record* provides objective evidence of the extent of the fulfillment of the requirements for quality or the effectiveness of the operation of a quality system element (ISO 8402). Some of the purposes of quality records are demonstration, traceability, and preventive and corrective actions. A record can be written or stored on any data medium.

16.1.2 NVLAP's quality system is documented through the use of quality records, which are valuable to NVLAP because they 1) provide assurance that the quality requirements for the accreditation service were satisfied; 2) show the degree of implementation and success of the quality system; and 3) provide a basis for measurement and feedback essential for continuous improvement. Quality system records maintained by NVLAP include:

16.1.2.1 management review (Sec. 1.3);

16.1.2.2 approved assessors (i.e., approved vendor list) (Sec. 6.2);

16.1.2.3 corrective and preventive action (Sec. 14.4);

16.1.2.4 internal audit (Sec. 17.3);

16.1.2.5 training (Sec. 18.4);

16.1.2.6 LAP design review (Sec. 4.6);

16.1.2.7 product inspection and release of conforming product (Sec. 10.5 and Sec. 12.1); and

16.1.2.8 customer satisfaction results (Sec. 19.4).

16.1.3 NVLAP maintains records to demonstrate that accreditation procedures have been effectively fulfilled, particularly with respect to application forms, assessment reports, and records relating to the granting, maintaining, extending, suspending or withdrawing of accreditation.

16.1.4 NVLAP records may be maintained either in hard copy or electronic format, or both.

16.2 AUTHORITY AND RESPONSIBILITY

16.2.1 Two laws primarily govern federal records management: the Federal Records Act of 1950, as amended, and the Paperwork Reduction Act of 1995. The former establishes the basis for records management programs in federal agencies; the latter gives records management a part of a broader program of federal information resources management.

16.2.2 Federal agencies such as NIST are required to have a records schedule approved by the Archivist of the United States that informs officials of the actions that must be taken with respect to the federal records in their offices.

16.2.3 Information about General Records Schedules, records management publications, disposition of federal records, definitions, and other information pertaining to federal records management is available on the Internet web site maintained by the National Archives and Records Administration, www.nara.gov.

16.2.4 Policies, responsibilities, and procedures for the management of records at NIST are prescribed in the *NIST Administrative Manual*, Subchapter 2.06, Records Management.

16.2.5 NVLAP responsibilities for establishing, collecting, filing, indexing, storing, and maintaining records are defined in the administrative procedure, APM 03.07, *Records Management*. Appendix A of this procedure, NVLAP Record List, specifies the following information for each type of record, including quality records:

16.2.5.1 person responsible for record review;

16.2.5.2 person responsible for record storage;

16.2.5.3 storage location;

16.2.5.4 disposal method;

16.2.5.5 retention period;

16.2.5.6 retention method; and

16.2.5.7 related procedures and instructions.

16.3 POLICY

NVLAP has the following policy regarding records:

16.3.1 Records should be clearly identified and traceable to the service involved, or to the quality system activity they document.

16.3.2 Records should be filed, indexed, and maintained in a manner that provides for safe storage and ready access or retrievability.

16.3.3 Records should be an accurate and truthful representation of actual events, documented in a timely manner.

16.3.4 Records should be dated and initialed or signed by the person(s) specified in the applicable procedures or instructions.

16.3.5 Personnel involved in collecting data for records should be provided instructions and training to the degree necessary to ensure that the records are generated correctly.

17.0 INTERNAL QUALITY AUDITS

Section 17 of the QSM addresses the requirements of clause 4.17 (Internal Quality Audits) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

17.1 GENERAL

17.1.1 NVLAP plans and conducts internal quality audits for the following purposes:

17.1.1.1 to verify whether quality activities comply with planned arrangements; and

17.1.1.2 to determine the overall effectiveness of the quality system.

17.1.2 There shall be a minimum of one internal audit per year. An audit may be completed at one time or on a rolling basis over a period of several months; i.e., specific requirements to be audited are scheduled for specific months.

17.1.3 An internal audit may be conducted by one or more audit teams. An audit team may consist of a cross-section of NVLAP employees who are independent, to the extent possible, of the operations being audited. Other NIST (non-NVLAP) employees may be invited to participate on an audit team or act as audit observers.

17.1.4 Internal audits are conducted in accordance with APM 03.03, *Internal Quality Audits*, using a prescribed checklist format and instructions to ensure consistency in approach between different auditors.

17.2 RESPONSIBILITIES

17.2.1 The Quality Manager is responsible for organizing and coordinating the internal audit. This includes the following activities:

17.2.1.1 establishing an audit team(s) and designating a team leader(s);

17.2.1.2 preparing the audit schedule and advising NVLAP Program Managers and staff of the audit program;

17.2.1.3 monitoring all investigative, reporting, and follow-up activities to ensure compliance with the internal audit procedure;

17.2.1.4 developing an audit checklist format and providing guidance to the team leader(s) in the development of checklist items which reflects the objectives and scope of the audit for each activity;

17.2.1.5 ensuring that the audit is conducted according to the audit schedule;

17.2.1.6 convening the NVLAP Quality Committee at appropriate stages in the audit process;

17.2.1.7 preparing an audit report listing each activity audited, the corresponding nonconformities found, and general observations; and

17.2.1.8 maintaining records which indicate that the whole process has been implemented effectively.

17.2.2 The Quality Committee has the following responsibilities relative to internal quality audits:

17.2.2.1 reviews team checklist/report submitted by the team leader(s) at the conclusion of the audit activities, ensuring that all findings are supported by objective evidence, adequately documented, and identified in terms of specific requirements;

17.2.2.2 makes the final determination as to which items will be reported to NVLAP management as nonconformances; however, the committee does *not* delete or modify an audit team's observations as recorded in the checklist;

17.2.2.3 comments upon and approves final audit report prepared by the Quality Manager before it is submitted to the NVLAP Chief;

17.2.2.4 issues Corrective Action Requests (CARs) in accordance with Section 14 of this manual; and

17.2.2.5 provides follow-up on outstanding audit action items until closure is achieved.

17.3 AUDIT RESULTS

17.3.1 The final audit report is presented to the NVLAP Chief and copies are distributed to the Management Committee and team leader(s).

17.3.2 Corrective/preventive action is undertaken by the manager of the audited operation if deficiencies are noted in either the quality system and procedures, or the performance and adherence to those systems and procedures.

17.3.3 The results of the internal audit are used as key input information for conducting the annual management reviews.

17.3.4 Records that document the internal audit process and results are kept for a period of 5 years by the Quality Manager.

18.0 TRAINING

Section 18 of the QSM addresses the requirements of clause 4.18 (Training) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

18.1 GENERAL

18.1.1 Investing in people through effective training is a key strategy for achieving the NVLAP Mission and Objectives for Quality.

18.1.2 Policies and procedures for the NIST Training Program are found in Subchapter 10.08 of the *NIST Administrative Manual*. The objective of NIST's program is to train and develop employees for maximum achievement of NIST goals and objectives in accordance with applicable laws and mission. Training is applied for, approved, and paid for in accordance with NIST training policy and procedures.

18.1.3 NIST management must treat all NIST employees fairly and consistently when considering requests for training. All NIST employees must be encouraged to increase their competence and given an opportunity to receive training to realize their utmost potential.

18.1.4 All NIST supervisors are required to complete training in a variety of core subjects as listed in the *NIST Administrative Manual*, Subchapter 10.08, Appendix B. These subjects deal with such topics as classifying and staffing positions, performance and conduct problems, health and safety responsibilities, incentive awards, etc.

18.1.5 Training and education opportunities for NIST staff are published weekly in the *NIST Technicalendar*.

18.2 TRAINING OF NVLAP STAFF

18.2.1 It is NVLAP's policy to identify the education and training needs and provide for the training of all NVLAP staff. Training is delivered to enhance and increase employees' knowledge, skills, and abilities required for successful performance of both current and future official duties, to increase efficiency and effectiveness of operations, and to maintain the requirements of NVLAP's quality system. NVLAP employees may request training at any time.

18.2.2 NVLAP supervisors are responsible for:

18.2.2.1 making decisions regarding education and training requirements for specific functions and positions;

18.2.2.2 discussing with employees developmental needs, professional goals and deficiencies;

18.2.2.3 encouraging training by being aware of opportunities, making recommendations, and providing regular feedback on performance;

18.2.2.4 providing on-the-job reinforcement of skills;

18.2.2.5 recommending approval of training, giving consideration to existing budgetary and personnel resources;

18.2.2.6 ensuring that incumbent staff members are retrained when they are assigned new duties or when operating methods are updated; and

18.2.2.7 evaluating the effectiveness of training given for the personnel they directly manage.

18.2.3 In addition, NVLAP supervisors are responsible for ensuring that new hires under their supervision receive training as follows.

18.2.3.1 New hires receive quality awareness training which covers the following topics to provide knowledge of NVLAP's quality philosophy and system:

- NVLAP's services and customers;
- Mission Statement and Quality Objectives;
- key concepts and documentation structure of ISO 9001/Q9001;
- quality organization, responsibility, authority, and structure in NVLAP; and
- the employee's role and responsibility for quality at NVLAP.

18.2.3.2 New Program Managers attend a recognized ISO 9000 Series Lead Assessor training course within the first 6 months of hire. Following completion of training, they must apply for certification as an ISO 9000 Series Auditor and obtain certification within the first year of hire. They are responsible for maintaining certification.

18.2.3.3 New Program Managers receive NVLAP assessor training (see 18.3.3 below).

18.2.3.4 New administrative staff attend a recognized ISO 9000 Series Quality System, Internal Auditor, and/or Documentation course, as specified by their supervisors.

18.2.4 Training is given to prevent the reoccurrence of nonconformities; for example, internal audit results may show nonconformities caused by lack of employee knowledge or skills, or customer feedback may indicate a need for improved telephone skills.

18.2.5 Final approval of all requests for training of NVLAP staff (conducted outside of NVLAP) is granted by the Director of the Office of Standards Services, who is the approving official.

18.3 TRAINING OF ASSESSORS

18.3.1 The NVLAP Chief is responsible for ensuring that all assessors are selected and trained in accordance with APM 22.01, *Assessors—Recruitment, Selection and Training*. The NVLAP Chief delegates this responsibility to the Program Managers for LAPs directly under their management.

18.3.2 Assessors are selected by Program Managers on the basis of defined criteria, including experience, communication skills, breadth of technical knowledge, laboratory management, quality assurance, professional activities, and education/training, as defined in APM 22.01 (also see QSM Sec. 6.2).

18.3.3 NVLAP conducts assessor training which addresses NVLAP policy and procedures, specifically NIST Handbook 150 and ISO/IEC Guide 25, as well as specific technical content for the targeted LAP. Each assessor receives a copy of the NVLAP Assessor Training Manual, customized for the specific LAP(s) for which he/she will be performing assessments.

18.3.4 All NVLAP assessors must successfully complete training before assessing laboratories to NVLAP requirements. Whenever economics and resources allow, each new assessor is accompanied by a qualified NVLAP assessor on one or more actual assessments.

18.3.5 Assessors who were qualified by NVLAP before the introduction of the selection and training requirements are "grandfathered" as qualified.

18.3.6 Assessor training is kept current through the issuing of memoranda or bulletins containing updated procedural or technical information. These are provided to all assessors (or assessors within a specific program, if appropriate) as necessary.

18.4 TRAINING RECORDS

18.4.1 All NIST-mandated training and probationary supervisor training records are maintained by the NIST Training Office.

18.4.2 NVLAP maintains copies of work-related education and training requests, which are filed by and stored in the office of the Administrative Support Assistant.

18.4.3 Employees are responsible for submitting training certificates, etc., indicating completion of training to the NIST Personnel Office for inclusion in their official personnel folders.

18.4.4 Program Managers are responsible for ensuring that all NIS and hard copy assessor training records are complete and up-to-date in accordance with APM 22.01.

19.0 SERVICING

Section 19 of the QSM addresses the requirements of clause 4.19 (Servicing) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994.

19.1 GENERAL

19.1.1 *Service* is defined as the results generated, by activities at the interface between the supplier (NVLAP) and the customer (laboratory) and by supplier internal activities, to meet customer needs (ISO 8402).

19.1.2 NVLAP manages customer interfaces in conjunction with OIM 03.01 (*Customer Service—Telephones*) and OIM 03.02 (*Customer Service—Requests for Information*).

19.1.3 NVLAP manages customer complaints based on the administrative procedure APM 24.02 (*Complaints, Appeals and Disputes*).

19.2 RESPONSIBILITY

19.2.1 The Business Manager is responsible for coordinating customer service activities at NVLAP, and for ensuring that appropriate records to document customer service performance are maintained.

19.2.2 All NVLAP employees are responsible for communicating with customers in a courteous and professional manner, listening to them, and keeping them informed. Staff give prompt attention to difficulties in communication or interactions with customers, as these difficulties often provide important information for improvements in service delivery.

19.3 SERVICE DELIVERY

Services that NVLAP delivers to its accredited customer laboratories include:

19.3.1 recognition that they comply with criteria which encompass the requirements of ISO/IEC Guide 25 and the relevant requirements of ISO 9002;

19.3.2 listing in the NVLAP directories of accredited laboratories (an annual hard copy directory and an Internet directory, which is updated quarterly);

19.3.3 a newsletter, *NVLAP News*;

19.3.4 provision of information about accreditation services, technical issues (in the form of laboratory bulletins and technical briefs), and requirement changes;

19.3.5 on-site assessments, including reviews of laboratory quality manuals;

19.3.6 program handbooks and guides in areas of accreditation offered by NVLAP; and

19.3.7 the authority to use the NVLAP logo and reference the term *NVLAP* in accordance with NVLAP conditions.

19.4 CUSTOMER SATISFACTION

19.4.1 NVLAP is committed to maintaining high levels of customer satisfaction. This commitment is manifest in NVLAP's customer service plan which includes the NVLAP mission statement, descriptions of its customers, services, and customer service standards, and plans for obtaining customer feedback and improving its services.

19.4.2 Customer assessment is the ultimate measure of the quality of service; therefore, NVLAP has instituted an ongoing assessment and measurement of customer satisfaction. These assessments seek positive as well as negative reactions and their likely effect on future accreditation services.

19.4.3 Assessment of service quality is accomplished in several ways.

19.4.3.1 A Customer Satisfaction Survey is conducted periodically, subject to approval of the OMB. Questions address service delivery characteristics such as responsiveness, accessibility, courtesy and helpfulness, competence, accuracy, user-friendliness, knowledgeability, and timeliness of communications.

19.4.3.2 Assessor Questionnaires are mailed to each laboratory after an on-site assessment is conducted by a NVLAP assessor. This information is used to monitor assessor performance.

19.4.3.3 A formal complaint system is in place to address customer (internal and external) concerns and complaints. The NVLAP Quality Committee provides a timely review of all logged complaints and their resolutions.

19.4.3.4 Customer comments received during meetings and workshops, as well as during the course of day-to-day business communications, are directed to the appropriate NVLAP managers.

Analysis of these data will measure achievement of service goals and indicate opportunities for improving service quality and the effectiveness and efficiency of the service provided.

20.0 STATISTICAL TECHNIQUES

► The requirements of clause 4.20 (Statistical Techniques) in ISO 9001:1994 and ANSI/ASQC Standard Q9001-1994 do not apply to NVLAP.

The following is a list of the acronyms used in this manual and their meanings.

ANSI:	American National Standards Institute
► APLAC:	Asia-Pacific Laboratory Accreditation Cooperation
APM:	NVLAP Administrative Procedures Manual
ASQC:	American Society for Quality Control
► BPA:	Blanket Purchase Agreement
CFR:	Code of Federal Regulations
COTR:	Contracting Officer's Technical Representative
DAO:	Department Administrative Order
DOC:	Department of Commerce
EAL:	European Cooperation for Accreditation of Laboratories
FAR:	Federal Acquisition Regulation
IEC:	International Electrotechnical Commission
ILAC:	International Laboratory Accreditation Conference
ISO:	International Organization for Standardization
ISO-CASCO:	ISO Council Committee on Conformity Assessment
LAP:	Laboratory Accreditation Program
► MLA:	Multilateral Agreement
MOU:	Memorandum of Understanding
► MPA:	NVLAP Management and Program Assistant
MRA:	Mutual Recognition Agreement
► NACC:	North American Calibration Cooperation

▸	NIS:	NVLAP Information System
	NIST:	National Institute of Standards and Technology
	NVLAP:	National Voluntary Laboratory Accreditation Program
	OIM:	NVLAP Operating Instructions Manual
▸	OMB:	Office of Management and Budget
	OSS:	Office of Standards Services
	QSM:	NVLAP Quality System Manual
	TS:	Technology Services
▸	USC:	United States Code
	WERB:	Washington Editorial Review Board

LIST OF REFERENCES

- ANSI/NCSL Z540-1-1994, *Calibration Laboratories and Measuring and Test Equipment—General Requirements*

- ISO/IEC Guide 2: 1996, *Standardization and Related Activities—General Vocabulary*

ISO/IEC Guide 25: 1990, *General Requirements for the Competence of Calibration and Testing Laboratories*

ISO Guide 30: 1992, *Terms and Definitions Used in Connection with Reference Materials*

- ISO/IEC Guide 43-1: 1997, *Proficiency Testing by Interlaboratory Comparisons—Part 1: Development and Operation of Proficiency Testing Schemes by Laboratory Accreditation Bodies*

- ISO/IEC Guide 43-2: 1997, *Proficiency Testing by Interlaboratory Comparisons—Part 2: Selection and Use of Proficiency Testing Schemes by Laboratory Accreditation Bodies*

ISO/IEC Guide 58: 1993, *Calibration and Testing Laboratory Accreditation Systems-General Requirements for Operation and Recognition*

ISO 8402: 1994, *Quality Management and Quality Assurance—Vocabulary*

ISO 9001: 1994, *Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*

ISO 9002: 1994, *Quality Systems—Model for Quality Assurance in Production, Installation, and Servicing*

- ISO 9004-2:1991, *Quality Management and Quality System Elements—Part 2: Guidelines for Services*

- ISO 10013:1995, *Guidelines for Developing Quality Manuals*

- NISTIR 5630 (April 1995), *NVLAP Comparison of NIST Handbook 150 with ISO/IEC Guide 58:1993*

CURRENT NVLAP INTERNAL COMMITTEES AND COMPOSITION

Management Committee:

J. Cigler, Chief (Chair)
D. Alderman, Deputy Chief (Vice-Chair)
J. Horlick, Technical Advisor
D. Faison, Sr. Program Mgr.
T. Davis, Sr. Program Mgr.
P. Martin, Sr. Program Mgr.
J. Crickenberger, Sr. Program Mgr.
V. White, Business/Quality Mgr.

Quality Committee:

V. White, Business/Quality Mgr. (Chair)
D. Faison, Sr. Program Mgr. (Vice-Chair)
T. Davis, Sr. Program Mgr.
L. Knab, Program Mgr.
S. Abrecht, Management & Program Asst.

Information Systems Committee:

D. Alderman, Deputy Chief (Chair)
V. White, Business/Quality Mgr. (Vice-Chair)
D. Faison, Sr. Program Mgr.
Contractor (Analyst/Programmer)

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The Table of Contents of the NIST Administrative Manual is now accessible on the NIST internal web site, http://www-i.nist.gov/admin/mo/adman/contents.htm. Due to the frequent updating of the contents on the web site and obsolescence of the hard copy versions, it is no longer practical to print the contents in this appendix. Please visit the web site for the latest listing.

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NVLAP®

CONFIRMATION SLIP FOR CHANGE CONTROL OF NVLAP QUALITY SYSTEM MANUAL

To the NVLAP Quality Manager:

I confirm that I have read and inserted the revised pages, Issue Date _____, into the *NVLAP Quality System Manual*, Copy No. _____, and confirm that the old pages have been discarded.

_____ (Signature)

_____ (Printed Name)

_____ (Date)

Please return this confirmation slip to:

National Institute of Standards and Technology
National Voluntary Laboratory Accreditation Program
Building 820, Room 282
Gaithersburg, MD 20899 U.S.A.

February 20, 1996

MEMORANDUM FOR Belinda L. Collins
Director, Office of Standards Services

From: Arati Prabhakar
Director

Subject: Delegation of Authority

This memorandum confirms long-standing policy at the National Institute of Standards and Technology (NIST) of delegating certain designated authority to the Chief of the National Voluntary Laboratory Accreditation Program (NVLAP). This delegation is in full accordance with the U.S. Code of Federal Regulations, Part 285, Subpart A, section 285.5.

Item 1 - Accreditation Actions

In order to ensure that NVLAP meets the requirements of ISO/IEC Guide 58, Calibration and testing laboratory accreditation systems - General requirements for operation and recognition, for the organization of an accrediting body, the Director of NIST has delegated to the Chief of NVLAP, and hereby confirms such delegation, responsibility for all NVLAP accreditation actions, including granting, maintaining, extending, suspending, or withdrawing any NVLAP accreditation.

Item 2 - Establishing a LAP

In order to ensure that NVLAP meets the requirements of ISO/IEC Guide 58, Calibration and testing laboratory accreditation systems - General requirements for operation and recognition, the Director of NIST has delegated to the Chief of NVLAP, and hereby confirms such delegation, responsibility for the establishment of laboratory accreditation programs (LAPs).

This delegation of authority should be reflected, wherever appropriate, in NVLAP publications such as NIST Handbook 150, NVLAP Procedures and General Requirements and the NVLAP Quality Systems Manual.

NOTE: Although NVLAP is encouraged to engage in discussions with representatives of the accreditation bodies of other countries which might lead to the development of Mutual Recognition Agreements, this delegation of authority does NOT extend to the conclusion of any agreements with the governments of other countries referenced in section 285.11(f) of the U.S. Code of Federal Regulations cited above.

cc: Peter Heydemann
James Cigler